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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,614	10/27/2003	Robert R. Brubaker	MSU 4.1-671	5738

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,614

Applicant(s)

BRUBAKER ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/17/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed on 10/27/03 is acknowledged.

Status of Claims

2. Claims 2-3 and 8 have been amended.

Claims 1, 4 -7 and 9 have been canceled.

Claims 2-3 and 8 are pending in the application and are under examination. A First Action on the Merits on these claims is issued.

Priority

3. It is noted that this application appears to claim subject matter disclosed in prior Application No 08/302,423, now U.S. Patent 6,638,510 B1 filed 9/8/04. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit under 35 U.S.C. 120, the reference must include the relationship (i.e., divisional) of all nonprovisional applications. Also, the current status of parent application should be included.

Information Disclosure Statement

4. Acknowledgment is made of an Information Disclosure Statements filed 10/27/03 and a signed copy of the same is attached to this Office action.

Claim Informalities

5. Please note the spelling "enclode" in claim 8. It should be "encode." Correction is required.

Claim Objections

6. MPEP 2173.05(s) states that Where possible, claims are to be complete in themselves. Incorporation by reference to a

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specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m).

Claim 2 refers to Figure 1. However, there is no guidance in the claim to which specific construct applicant is referring to?

7. MPEP: 2173 also states that claims must particularly point out and distinctly claim the Invention. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

Claim 2 recites Figure 1. However, figure 1 contains several plasmids and there is no practical way of defining the invention (protein) clearly.

8. MPEP § 608.01(m):

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims.

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Claim 3 is also objected to because they include reference characters, which are not enclosed within parentheses.

Rejection(s) under 35 U.S.C. § 101

9. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

10. Claims 2, 3 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. To overcome this rejection the Examiner suggests the amendment of the claims to include "isolated" so that it is "free of" relative to the natural source. (see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

11. Claim 3 is rejected under 35 U.S.C. 101 because it is inoperative because claim does not set forth which protein is capable of inducing protective immunity.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his/her invention

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13. Claims 2, 3 and 8 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it fails to recite structure, function and property of a protein.

Claims 2 and 8 recite "an antigen protein". In general, all proteins are multideterminant antigens. Therefore, it is not clear what applicant is claiming?

Claim 2 is vague and indefinite in the recitation of "plasmid having the construct shown in figure 1" because it is not clear which protein is encoded by which construct and which plasmid?

Claim 3 is vague and unclear in the recitation of "(v antigen) and (anti-v antigen)". It is not clear what does it mean? It is also not clear whether "(v antigen) and (anti-v antigen)" is intended to be a limitation of the claim.

Claims 3 and 8 are rejected as being vague and indefinite for the recitation of "capable of ". The expression "capable of " used in the claim renders the claim indefinite because the metes and bounds of the term "capable of " is unclear.

Claim 8 is rejected as vague for the recitation of "ability to encode." The expression "ability " used in the claim renders the claim indefinite because the metes and bounds of the term "ability" is unclear.

Claim Rejections - 35 USC 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 2,3 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Motin et al 1994 May Abstracts of the General Meeting of the American Society for Microbiology, Vol.94, pp 155. Abstract only

Claims 2 and 3 are drawn to antigen protein encoded by plasmid having the construct shown in Figure 1 and a protein (V antigen) capable of inducing a protective antibody of (anti-v antigen) response. Claim 8 is drawn to an antigen protein encoded by a plasmid prepared by recombinant techniques comprised of an ability to encode proteins capable of controlling the effects of *Y. pestis*, the plasmid containing low calcium response regions V and H and the structural gene for staphylococcal protein A.

Motin et al disclose 37.3 - kDa monomeric peptide encoded on the ca. 70-kb Lcr plasmid *Yersinia pestis*. This peptide has been implicated as a regulator of the low-calcium response, virulence factor, and as a protective antigen. lcrV of *Y. pestis* with was cloned into protease-deficient *Escherichia coli* BL21, after expression of the lcr GVH operon under the tac promoter. Plasmid pPAV13 was constructed so as to encode a fusion of lcrV and the structural gene for protein A (i.e., all but the first 67 N-terminal amino acids of V antigen plus the signal sequence

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and IgG-binding domains but not the cell wall-associated region of protein A). The resulting fusion peptide, termed PAV was purified and Rabbit polyclonal gamma globulin was made against PAV and was used to provide excellent passive immunity against 10 min. LDs of *Y. pestis*. The prior art anticipated the claimed invention.

16. Claims 2 –3 are rejected under 35 U.S.C. 102(b) as being anticipated by Perry et al Infect Immun. 1986 Nov; 54(2): 428-34

Claims 2 and 3 are drawn to antigen protein encoded by plasmid having the construct shown in Figure 1 and a protein (V antigen) capable of inducing a protective antibody of (anti-v antigen) response.

Perry et al disclose a 38kD V antigen protein in a plasmid construct pCD1 (see abstract and figure 4). Further, the prior art teachings show that this V antigen is a protective antigen (page 428, left column). In the absence of the characteristics of the claimed protein, the prior art anticipated the claimed invention.

17. Claims 2 –3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergman et al et al 1991 Journal of Bacteriology, 173; 1607-1616.

Claims have been discussed supra

Bergman et al disclosed V antigen in a plasmid construct pTB71 (see abstract and Table 1). Further, the prior art teachings show that this V antigen is a regulatory protein (page 1610, left column). In the absence of the characteristics of the claimed protein, the prior art anticipated the claimed invention.

18. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Watson et al 1988 Infect Immun. 1988 May; 56(5): 1358- 1363.

Claim 3 is drawn to a protein V antigen capable of inducing a protective antibody of (anti-v antigen).

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Watson et al disclose antigen complex V-1 (see abstract) from *M.pulmonis*, monospecific antiserum and monoclonal antibodies to V-1 (see page 1359, left column). The prior art anticipated the claimed invention.

19. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Straley et al 1986, Infect Immun; 51(2): 445-454.

Claims have been discussed supra

Straley et al disclose V antigen in a plasmid pCD (see abstract and page 449, lower left column) The prior art anticipated the claimed invention.

Remarks

20. Claims 2, 3 and 8 are rejected.

21. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

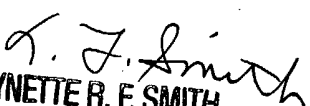
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature

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or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

5/11/04


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